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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,367	01/03/2002	Sophie M. Carpentier	ECV-5608	9800

7590 07/06/2004

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EXAMINER	
EINSMANN, MARGARET V	

ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,367	CARPENTIER ET AL.	
	Examiner	Art Unit	
	Margaret Einsmann	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-92* is/are pending in the application.

4a) Of the above claim(s) *21 and 25-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election of Group I, claims 1-20, 22-24 in the reply filed on 5/26/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20 and 22-24 are being examined in this action.

Information Disclosure Statement

The Information Disclosure Statement received May 28, 2002 has been considered and returned with this action. A transmittal letter and references were received on January 26, 2004 but there is no 1449 in with the submitted papers. The references received on that date which have been considered by the examiner have been listed on the 892.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following terms are so indefinite that their metes and bounds cannot be determined. "a first temperature," "a first period of time," "a second temperature" and "a second period of time." Furthermore when the first temperature and the second temperature are defined in the dependent claims they contain overlapping ranges. For

example, the first or second temperature of 70° C meets the limitation of each of claims 3,4,5,and 7. All of those claims include a process in which the first temperature is 69.5 °C. and the second temperature is 70° C. That is a normal variation even when using a thermostat.

Claim 2 is further indefinite for the following reasons. There is no antecedent basis for the starting pH of 7.4. Since the starting pH is not defined, we cannot determine the numerical change in pH from the second requirement, a fall in pH of 20%. Regarding the third requirement, how does one determine when the solution is yellow or brown? What color is the starting solution? If it is clear, surely will pass through a shade that could be considered yellow before it turns brown. And how brown is brown? How does one make the determination if the solution has turned to yellow or to brown?

Regarding claim 10, the ranges are open ended.

Regarding claims 13-17, immersing bioprosthetic tissue in glutaraldehyde is a fixation step in itself. See Carpentier et al, WO 60/4028A1 page 2 lines 6-18. Accordingly, said tissue is being fixed concurrently with the process of claim 1.

Regarding claim 18, it is broader than and not properly dependent on claim 17 which limits the fixative agent to non-heat treated glutaraldehyde.

In claim 20, the term "further" should be deleted from the first line as the claim does not disclose a further treatment but merely spells out the temperature and time ranges of the method as claimed in claim 1. Also in claim 20, the range of the heating step in inclusive of the second temperature.

Regarding claim 24,Claim 24 contains the trademark/trade name Tween 80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the surfactant in the composition and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 7-9, 11, 13-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIlroy et al, US 6,093,530. In example 1, in the paragraph bridging columns 5 and 6, McIlroy discloses the following standard method of tanning tissues

with glutaraldehyde. Tissue samples were fixated by three successive immersions in 0.3% glutaraldehyde in phosphate buffered saline (ph 7.3) for 24 hours each at 40° C., room temperature, and 37° C. respectively, with transfer to fresh solution between each immersion. Accordingly glutaraldehyde was heated to a first temperature for a first period of time (from 0° to room temperature) which was maintained for a first period of time (24 hours) and the temperature of the glutaraldehyde was adjusted to a second temperature (37°C.) and the tissue was contacted with the glutaraldehyde for a second period of time (24 hours). The reference fails to state that the temperature of the glutaraldehyde was adjusted to the second temperature before the tissue was immersed into it.

It would have been obvious to the skilled artisan that the temperature was adjusted prior to the tissue being immersed into the solution or just after the tissue was immersed in the solution, and it appears to be irrelevant when the temperature was adjusted since the temperature was kept at the adjusted temperature for the entire 24 hours that the tissue was immersed, and the short time it would take to raise the temperature from room temperature to 37° C is inconsequential when considering the total time of immersion.

Claims 1, 3, 7, 8, 11-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter International Inc, WO 96/04028.

Baxter discloses a process in which bioprosthetic tissue is fixed in glutaraldehyde at room temperature for at least three hours, then in glutaraldehyde heated to 35-55° C. for 4-22 weeks, and then stored in glutaraldehyde at room temperature for a time until

needed. The first temperature is room temperature reading on the limitation of claim 3. The second temperature is 35-35 reading on the limitation of claims 7 and 8 and also on claim 9 since the temperature range in claim 9 is indefinite. Alternatively, one can say that the first temperature is 35-55 and the first time is 4-22 weeks, and that the second temperature is room temperature and the second time is the time from beginning of storage until the bioprosthesis is implanted. In that case the limitation of claim 12 could certainly be met. Regarding claims 13-16, the fixation occurs at all stages of the process as disclosed in figure 2. See Figure 2 and its description beginning on page 9 line 30. The reference fails to state that the temperature of the glutaraldehyde was adjusted to the second temperature before the tissue was immersed into it.

It would have been obvious to the skilled artisan that the temperature was adjusted prior to the tissue being immersed into the solution or just after the tissue was immersed in the solution, and it appears to be irrelevant when the temperature was adjusted since the temperature was kept at the adjusted time for the entire time that the tissue was immersed, and the short time it would take to adjust the temperature is inconsequential when considering the total time of immersion.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIlroy et al or Carpentier et al. as applied to the claims above, and further in view of Nashef et al., US 4,885,005. Baxter and McIlroy are relied upon as in the above rejections as disclosing the standard treatment of bioprosthetic tissue to mitigate post implantation calcification by fixating in glutaraldehyde. They do not disclose the further

bioreduction treatment as claimed in claims 22-24. Nashef et al disclose the further treatment as claimed. In example 5 in column 6, glutaraldehyde fixated tissue from example II was treated in a solution containing 4% formaldehyde, 22.5% ethanol and 1.5% by weight Tween 80, which is the composition claimed for use in the method of applicant's claims 22- 24.

It would have been obvious to the skilled artisan to treat a bioprosthesis which had been fixated with glutaraldehyde further with the surfactant composition as disclosed in patentee's example V because Nashef teaches that a bioprosthetic tissue which had been treated with glutaraldehyde and subsequently treated with a surfactant composition unexpectedly and beneficially effected a sustained mitigation or reduction of calcification after implantation. See column 1 lines 41-52.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret Einsmann whose telephone number is 571-272-1314. The examiner can normally be reached on 7:00 AM -4:30 PM M, Tu,Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

July 1, 2004

Margaret Einsmann
Primary Examiner
Art Unit 1751